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DOSE APPROPRIATENESS AND ADJUSTMENT OF DRUGS IN CHRONIC KIDNEY FAILURE PATIENTS IN A TERTIARY CARE HOSPITAL OF TELANGANA

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ABSTRACT: Background: Dose appropriateness in Chronic Kidney Disease patients is crucial to avert toxicity since several drugs are eliminated through kidneys. The present study was taken up to identify the degree of appropriateness in the dosage regimen of patients with chronic kidney disease (CKD) patients. **Methods:** The study was a prospective observational study carried out in the Department of Nephrology in a tertiary care hospital of Telangana for 6 months. Patients diagnosed with CKD were included in the study, and the data regarding the demographic details, stage, prescribed drugs, *etc*., were obtained from the patients' medical records. The creatinine clearance was estimated using Cockcroft Gault (CG) equation. The dose appropriateness was compared with the guidelines and published literature. **Results:** Out of 274 CKD Patients admitted, 200 were included in the study, amongst 35 % of the patients were in the age group of 61-75 years, followed by 41-60 years of age (33%). Almost 94.5% of patients were found to have co-morbid conditions with diabetes, hypertension and heart function disorders as the most prominent ones. More than 5 drugs were the average number of prescribed drugs per prescription entry. 37% of prescription entries were found to have dose inappropriateness, and 33% of drugs were adjusted appropriately. **Conclusion:** The present study points out that dosing errors were observed in patients with CKD. Pharmacist intervention in dosing, upgrading of knowledge regarding dose adjustments may progress and lead to quality enhancement of prescription as well as dodge adverse drug reactions.

INTRODUCTION: A normal renal function is necessary for the metabolism and excretion of several drugs and their active metabolites.

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Impaired renal function may lead to accumulation of excess amounts of parent drugs and their metabolites [1]. In addition to this, renal failure may also influence the pharmacokinetic parameters like distribution concerning reduced plasma protein binding of the drugs and metabolism about several impaired functions of metabolizing enzymes and transporters [2]. Kidneys are vital components for regulating homeostasis, electrolytes, and acid-base equilibrium [3]. Dosing of drugs is one of the significant drug-related issues in patients with renal

impairment and may lead to ineffective therapy or toxicity if done inappropriately [4, 5]. Chronic Kidney Disease (CKD) may be defined as a type of kidney disease where there is a gradual loss of function taking place over a while.

It may be presented as reduced Glomerular filtration rate (GFR) < 60 ml/min together with structural abnormalities for more than three months. Irrespective of its etiology CKD may be classified into five stages. GFR or Creatinine Clearance (CrCl) is pertinent for the purpose of staging CKD [6]. It is estimated that approximately 5 to 10 million deaths are attributed to kidney failure cases every year [7].

The global prevalence of CKD cases is about 8-16% per year, with an average of about 80% mortality observed in developing countries [8]. CKD interrelates to drugs administered based on Patients susceptibility, pharmacokinetic and pharmaco-dynamic modifications [9]. It is essential for a physician to know about the stage of CKD in patients, which aid in the adjustment of drug dosage, preventing any potential toxic effects [10].

The dosing adjustment in renal impaired patients is based on the GFR or CrCl. There are many equations proposed for the calculation of Creatinine clearance, among which Cockcroft Gault equation provides an appropriate estimation of CrCl [6]. Drug toxicity and accumulation may develop if dosages were not properly adjusted. Further, patients with CKD may take a varied number of medications for progressive prevention of disease and other co-morbidities present.

Appropriate prescribing of doses in CKD patients may optimize drugs efficacy and help reduce the rapid development of toxicity and drug accumulation [11, 12]. Various literature studies reveal that the dose adjustments required in CKD patients are not appropriate and are seen in underdeveloped, developing and developed countries.

A study in Australia reported a high level of inappropriateness in elderly CKD patients with diabetes [13]. Similar results were also observed in another study where CKD patients with stages 3 and 4 revealed a high level of inappropriateness in the Netherlands [14].

Further, many studies also proposed 19-67% and 69% of non-compliance with renal dosing guidelines in hospital and ambulatory settings, respectively [15]. Many settings also implemented dose adjustment alerts, but variable results were observed with less significance of appropriateness in dosing. While managing CKD patients, the most common dosing error is those observed during antimicrobial use, requiring a lookout and adjustment in these patients depending on the eGFR of patients [16, 17].

Studies from China showed antibiotics related dosage errors in CKD patients were 38.5% to 60.3% [18, 19]. Thus captivating all the above facts and the availability of inadequately published literature in India regarding the degree of the inappropriateness of drug dosing, the present study was taken up to investigate the dose adjustment appropriateness of drugs prescribed in renal impairment patients who were admitted in a tertiary care teaching hospital of Telangana.

METHODOLOGY:

Study Design: A prospective observational study was carried out at the Department of Nephrology, BBR super specialty hospital, a tertiary care hospital of Telangana state, India. All the studies were performed after the prior approval of the institutional ethics committee (Protocol no: IEC/SIIP/PD/06-0003). In addition, verbal informed consent was obtained from all the patients who participated in the study.

Inclusion Criteria: All patients with CKD visiting the hospital from August 2019 to January 2020 were enrolled.

Patients with 15 years of age or above diagnosed with CKD, who were prescribed with not less than one pharmacological agent, hospitalized for at least one day were included in the study.

Exclusion Criteria: Female patients who were pregnant and patients with ages below 15 years were excluded from the study.

Also, Patients who were taking Ayush treatment or any other therapies like homeopathy, Unani and Siddha medicines were also excluded from the study.

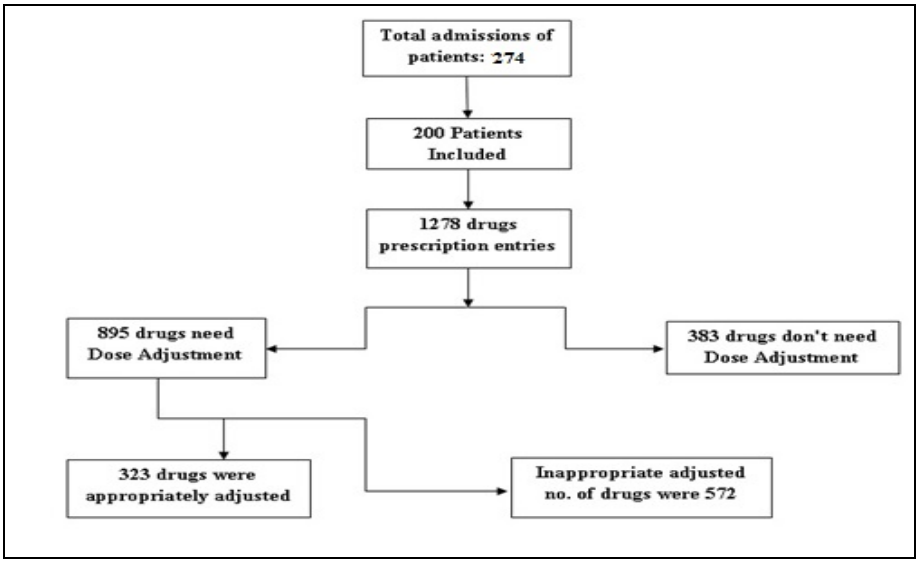

FIG. 1: STUDY DESIGN

Sample Size: All patients Admitted in the Department of Nephrology during August 2019 to January 2020 were considered for sampling purposes. From 274 admissions, only 200 patients were included in the final analysis based on the inclusion criteria.

Data Collection: Data of individual patients were collected from patient's medical records, which includes 1) Patients demographic details 2) Co-morbid conditions, 3) Reason for admission, 4) Serum creatinine levels, 5) Blood Urea Nitrogen, 6) Medications prescribed during hospitalization, etc. Data abstraction format was used for medications that require dose adjustment.

Subsequent to the data collection, the dose appropriateness was dogged by comparing the prescribed doses with the established suggestion "Drug Information Handbook" by Lexicomp® 20 and drug prescribing guidelines for adults and children by Aronoff *et al.*, 2007 [21] and other published literature, where the dose adjustments were difficult to find.

In order to compare dose appropriateness, the exact stage of the disease was to be determined. In the present study, the stage of the disease was confirmed with the help of the CG equation, which requires the estimation of Creatinine Clearance against age, weight, and levels of serum creatinine of the patient. The equation for calculation is as given below. For those patients who were in critical condition or immovable state, either the patient, if conscious or the most recent weight given by the patient caregiver was used.

$$\text{Men: Cr Cl (ml/min)} = [(140\text{-age}) \times \text{weight (kg)}]/\text{SCr(mh/dl)} \times 72$$

$$\text{Women: Cr Cl (Ml/min)} = [(140\text{-age}) \times \text{weight (kg)}]/(\text{SCr(mg/dl)} \times 72$$

Statistical Analysis: A descriptive analysis was made for the demographic data obtained *viz*., Age, Bodyweight, Creatinine value, Blood Urea Nitrogen, Average drugs prescribed per prescription, *etc*. The data was summarized and described using tables and graphs. The Relationship between dosing inappropriateness with that of different variables was analyzed using multivariate analysis like the Chi-square test. The significance level was set up at $p<0.05$.

RESULTS: In the present study, **Table 1** represents patients demographic and clinical characteristics included in the study. Out of 200 patients included, the majority of the patients were in the age of 61-75 years (33.5%) followed by 46-60 years (33%) and 31-45 years (13.5%), respectively. The least percentage of patients (8%) were found to between 16-30 years of age. The majority of CKD patients were male (88%) and Females affected with CKD were 44%, respectively **Table 1.** The average Body weight of the patients was found to be 63.895 ± 2.014 kg. The mean value of Serum creatinine was found to be 6.4803 ± 1.123 mg/dl and Blood Urea Nitrogen was found to be 111.695 ± 2.001 mg/dl. The stages of CKD were determined accordingly by

calculating the Glomerular filtration rate by CG formula. In the present study, 82.5% of the patients were of stage 5 CKD followed by 15% of patients with stage 4 and 2.5 % of patients with stage 3, respectively **Fig. 2.** Almost 94.5 % of patients were found in have one or more co-morbidity and only 5.5 % of patients were without any existing conditions. Hypertension and Diabetes were the most observed co-morbidities **Table 1.** The mean serum creatinine levels were highest, with 7.06 ± 1.056 mg/dl in stage 5 patients. Stage 4 and 3 patients were observed with 3.28 ± 1.245 mg/dl and 1.99 ± 0.998 mg/dl respectively. The blood urea nitrogen levels were proportional to Sc.cr levels, with the highest mean level being 109.75 ± 1.325 mg/dl in stage 5 patients of CKD **Fig. 3.**

TABLE 1: DEMOGRAPHIC AND CLINICAL DATA OF PATIENTS WITH CKD

Total number of hospitalized patients during the study period	**Clinical data number (%)358**
Total number of patients included in the study as per the criteria	200
Number of patients with renal impairment	195 (97.5%)
Male	112 (56%)
Female	88 (44%)
Age in years: 0-15	0 (0%)
16-30	16 (0.08%)
31-45	27 (13.5%)
46-60	66 (33%)
61-75	67 (33.5%)
75-90	24 (12%)
Body Weight (Mean ± SD)	63.895 ± 2.014
Serum creatinine (Mean ± SD)	6.4803 ± 1.123
Estimated Creatinine Clearance (Mean ± SD)	11.95022 ± 1.924
BUN (Mean ± SD)	111.695 ± 2.001
Drugs per patient (Mean ± SD)	10 ± 0.458
Drugs requiring dose adjustment per patient (Mean ± SD)	3.28 ± 2.354
Patients with stage of CKD :	
Stage 3	5 (0.025%)
Stage 4	30 (15%)
Stage 5	165 (82.5%)
Reason for admission:	
Renal related	195 (97.5%)
Non- renal	5 (2.5%)
Co-morbidity:	
Present	189 (94.5%)
Absent	11 (5.5%)
Type of Co-morbidity:	
HTN + DM	146 (77.24%)
HTN	11 (05.6%)
HTN + DM + CAD	32 (16.98%)

BUN: Blood Urea Nitrogen; HTN: Hypertension; DM: Diabetes mellitus; CAD: Coronary artery disease

The average number of drugs prescribed per prescription was 10 ± 0.458 **Table 1.** Many categories of drugs were prescribed to CKD patients during their stay in the hospital as well as after the discharge. 1298 drugs were on the whole Prescribed to the patients of which majority include Antibiotics (178), Anti-hypertensives (173); Anti-diabetics (143), Anti-emetics (156), Proton pump inhibitors (164) followed by Multivitamins, NSAIDs, Cardiovascular drugs, Antacids, *etc*. **Fig. 4** the prescribed medications were subjected to evaluation of dose adjustment criteria depending upon the stage of the disease.

The prescription entries constituted for about 1298 drugs, out of which 33% of the drugs were appropriately adjusted and 37% of drugs were found inappropriate dose adjustment and 30% of the drugs were not adjusted at all **Fig. 5.** The dose adjustment inappropriateness was found to increase as the stage of the disease progressed **Fig. 6.** Out of all the drugs prescribed, high amounts of inappropriateness were found in Antibiotics followed by GIT drugs, cardiovascular, corticosteroids and Anti-platelet agents (**Fig. 7.** Cefixime and Ceftriaxone were the most inappropriately prescribed antibiotics Fig. **8.**

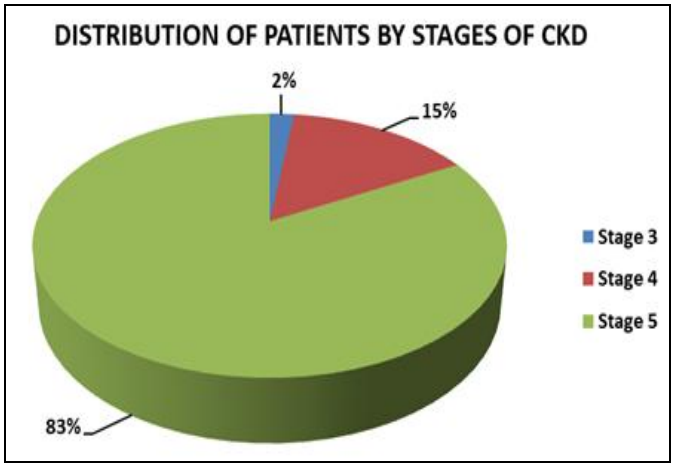

FIG. 2: DISTRIBUTION OF PATIENTS BY STAGES OF CKD

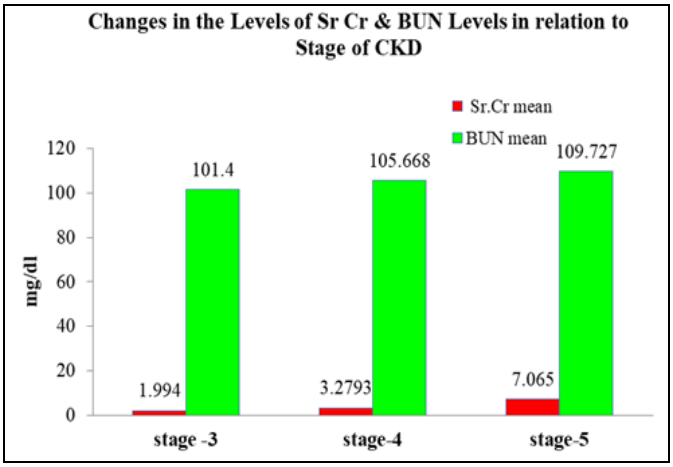

FIG. 3: CHANGES IN THE LEVELS OF SR CR & BUN LEVELS IN RELATION TO STAGE OF CKD

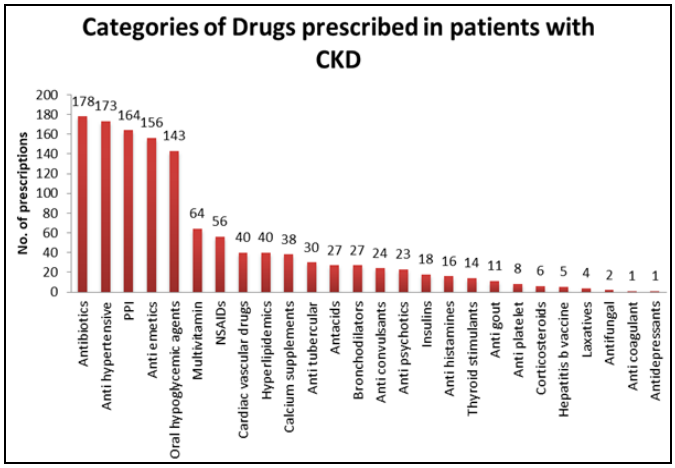

FIG. 4: DISTRIBUTION OF DRUGS PRESCRIBED IN PATIENTS DRUGS

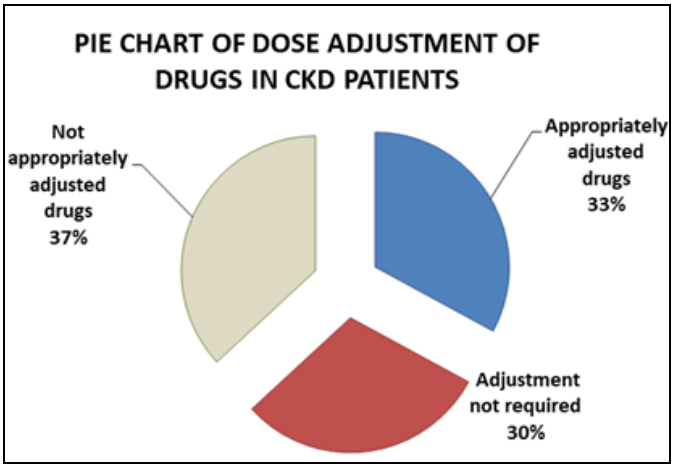

FIG. 5: PIE CHART OF DOSE ADJUSTMENT OF CKD IN CKD PATIENTS

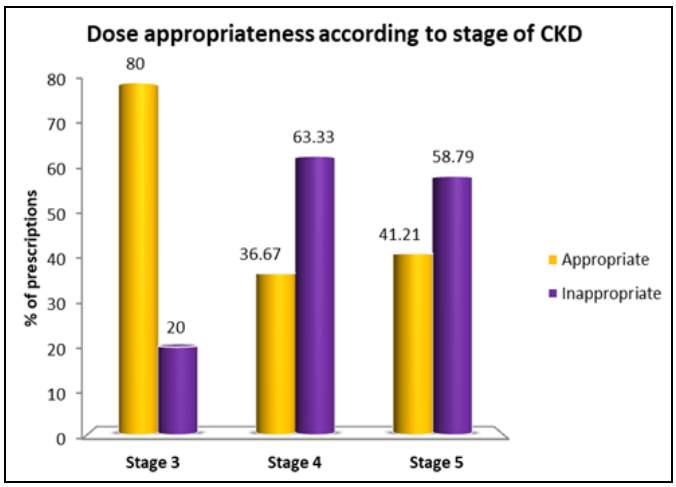

FIG. 6: DOSE APPROPRIATENESS ACCORDING TO STAGE OF CKD

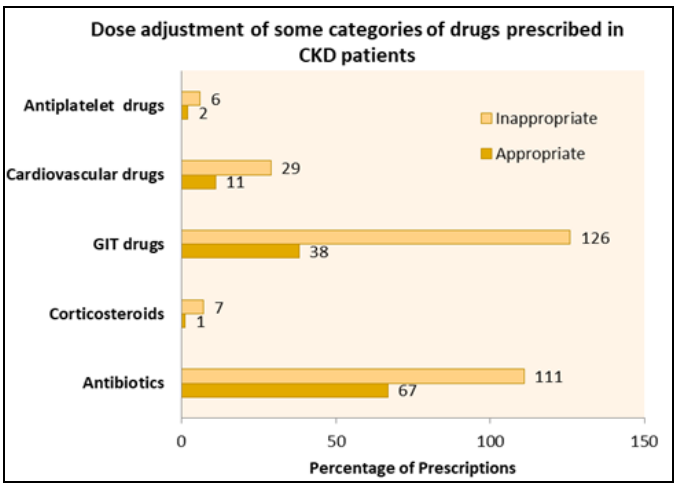

FIG. 7: DOSE ADJUSTMENT OF SOME CATEGORIES OF DRUGS PRESCRIBED IN CKD

Table 2 Represents the logistic regression analysis of different variables with that of dosing inappropriateness. The study revealed that patients above 65 yrs of age have more inappropriateness than patients below 65 yrs of age (OR=0.34).

The study also showed that gender differentiation in dose adjustment where males had more inappropriateness than females (OR=2.77). The drug inappropriateness differed according to the stage of the disease.

TABLE 2: RELATIONSHIP BETWEEN INDEPENDENT VARIABLES AND INAPPROPRIATELY ADJUSTED DRUG DOSES PER PATIENT

Variables	Inappropriate adjusted		p-value	Odds Ratio (95% Cl)
	Yes	No		
Age			0.0002*	0.34 (0.51, 0.62)
< 65 years	147	106		
65 and above	209	99		
Gender			0.0002*	2.77 (1.56 , 4.95)
Male	70	42		
Female	33	55		
Reason for admission			0.035*	23.51 (1.27 , 431.61)
Renal	133	62		
Non renal	0	5		
Stage			0.19	
Stage 3	1	4		0.1447 (0.014 , 1.464)
Stage 4	19	11		1.210872 (0.542 , 2.707)
Stage 5	97	68		
Sc cr	3.56	1.67	0.789	
BUN	106.85	79.49	0.063	
Co-morbidity			0.352	1.31 (0.33 , 5.08)
Present	62	127		
Absent	3	8		
No of Medications prescribed Per patient (Mean)	5.31	7.14	0.224	1.29 (0.79, 2.09)
No of Medications need Dose adjustment per patient (Mean)	1.68	2.4	0.19	1.47 (0.44, 4.45)

* The chi-square test is significant at p<0.05

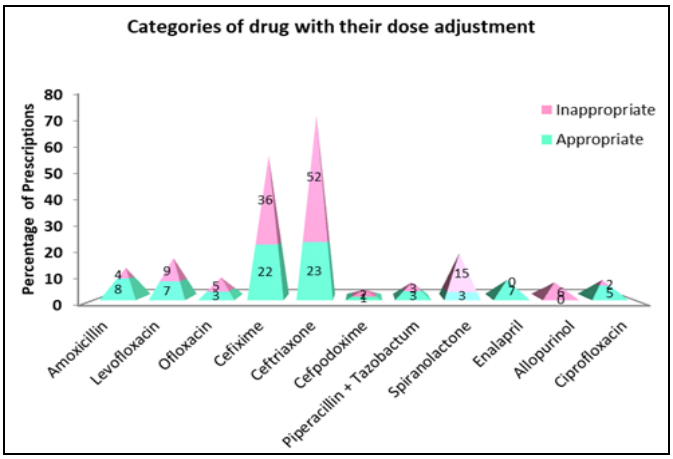

FIG. 8: DIFFERENT CATEGORIES OF ANTIBIOTICS PRESCRIBED IN CKD

DISCUSSION: The present study revealed the degree of appropriateness of drug doses prescribed in patients with Chronic Kidney failure. The descriptive analysis of the demographic facts of the patients yielded that majority of the patients belonged to the age group of 45-60 years and 61-75 years of age, which was according to a previous study conducted by Ahsan Sharma & Imran Massod [22]. In patients with CKD, the pharmacokinetic parameters like bioavailability, the volume of distribution, biotransformation and protein binding, and renal elimination are altered. This feature is significant for drugs whose major excretory route is through renal route [23], which ultimately influence the absorption pattern, hepatic and biliary metabolism that may lead to augmentation of pharmacological activity and toxic effects. Medication dosing errors are one of the most significant drug-related issues in patients with CKD. Drug-related issues may result in an increase of mortality and morbidity and increased adverse drug events, which may reflect by an increased hospital stay, unnecessary utilization of health care and overall economic burden. Many adverse events of drugs are predictable and can be prevented [23]. To shun any risk of complication in CKD patients, the doses are to be adjusted based on CrCl levels, co-morbid conditions and other co-prescribed medications [24, 25]. Physicians become more careful in prescribing medications and adjust the doses to patients with elevated Sc Cr levels. Out of 160 drugs prescribed, 33% of drugs were appropriately prescribed from the present study and 37% of drugs were dosed inappropriately. The extent of inappropriateness was compared with published literature and WHO guidelines. The present study revealed 37% of drugs were inappropriately prescribed according to WHO guidelines. Most of those drugs were antihypertensive drugs like Furosemide, Spironolactone, Amlodipine, Prazosin

followed by antibiotics. Other drugs like oral antidiabetic drugs, antiemetics, proton pump inhibitors and NSAID's were additionally prescribed. The result of the inappropriateness differed with previous studies like Decloedt *et al*., 19% and Sweileh *et al.* 79% [23, 24], [26]. The degree of inappropriateness was 37% which was high when compared with the above-reported studies. In assessing the medication dosing error pattern, most antibiotics were prescribed without any consultation of dose adjustment guidelines, including Cephalosporin's, Cefotaxime, Cefepime, and other drugs like Ranitidine Sodium bicarbonate, Metoclopramide, *etc*. The possible reasons for the predominance of antimicrobials were frequent usage, critical care unit, preoperative conditions, and careless use. Cardiovascular medications require frequent dose adjustment after antimicrobial agents. Although there is a high need for dose adjustment in renal impairment cases, the adjustments were to be made according to clinical responses [27, 32, 33].

The drug dose adjustment strategy should be followed to individualize drug therapy and improve safety and efficacy. The principles to improve the safety of prescription in CKD patients are to select appropriate drugs to consider possible drug interactions. An initial assessment of history, physical examination, CrCl calculation, selection of loading and maintenance dose, and monitoring of narrow therapeutic margin drugs may assist in a step-wise approach for physicians in prescribing [11, 19, 28, 29]. The varied rationale may be cited for this inappropriateness. The increasing number of drugs requiring dose adjustment in renal impairment makes it difficult for physicians to update themselves. The next reason may be the lack of knowledge on Cr Cl. Using Sc Cr level as the only indicator of renal function is not accurate. Rapidly changing Sc Cr values and fluctuating renal function might not permit the estimation of renal function. On the other hand, the assessment of CrCl requires 24 h urine collection, which is often difficult to perform and thus can be calculated with Cockcroft Gault Formula taking into consideration of the patient's weight, age, and Sc Cr level [18]. This equation yields a more conservative estimation and indicates the need for dose adjustment more often. It is quite conceivable that in addition to consideration of renal function, the prescribers may have made dose adjustments based on other parameters like blood pressure, heart rate, and electrolyte imbalance [27]. Prescribers should also be made available with charts regarding dose adjustment. Clinical pharmacologist**'s** involvement may achieve better therapeutic monitoring. Execution of computing system would be a better approach in providing the laboratory data, That is adaptable by the prescribers to analyze and observe CKD patients' renal function and thus reduce the in-appropriate dosing [30, 31]. When the recommendations were not available for specific drugs or are not clear enough, those drugs were to be compared to available literature sources. The significant differences in recommendations for the same drugs dosages can also complicate drug dosage in CKD patients.

CONCLUSION: In conclusion, this study reveals the significance of implementing dose adjustments in renal impairment patients. The study findings also suggest the need for providing physicians with information and guidelines that are up to date that can improve the overall outcome of the patient treatment and reduced toxicity. The interventions like computer-assisted programs, training of individuals in pharmacokinetic parameters, and regular monitoring would help in better compliance of a patient.

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CONFLICTS OF INTEREST: Authors declare that there are no conflicts of interest to report.

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